ES cont'd

94. The method of any one of claims 1, 55, 60, or 75, wherein the anti-CD3 antibody and the anti-CD28 antibody are directly immobilized on the solid phase surface.

REMARKS

Claims 1, 55, 60, 75, and 87-94 stand pending in the instant application. Claim 91 has been amended herein to remove dependencies upon claims 60 and 75. This Amendment After Final does not introduce new subject.

Former Rejections

Applicants acknowledge the withdrawal of the former rejections of (i) claims 56-59, 61-74 and 76-86 (Office Action, page 2, paragraph 3); (ii) claims 1, 55, 60, and 75 under 35 U.S.C. § 112, first paragraph (Office Action, page 2, paragraph 4); and (iii) claims 1, 55, 60, and 75 under 35 U.S.C. § 112, second paragraph (Office Action, page 3, paragraph 6).

Rejection under 35 U.S.C. § 112, First Paragraph

Claim 91 was rejected under 35 U.S.C. § 112, first paragraph, for purportedly lacking enablement (Office Action, page 2, paragraph 5). Specifically, the Examiner stated that "[o]ne of ordinary skill in the art would not reasonably expect that . . . a tissue culture plate could be employed *in* vivo." Without acquiescing in the propriety of the rejection, Applicants have herein amended claim 91 to remove the dependencies of the claim to *in vivo* claims, *e.g.*, claims 60 and 75. Amended claim 91, therefore, now depends only on *in vitro* method claims. Applicants respectfully contend that this rejection has been obviated and should be withdrawn.

Rejection under 35 U.S.C. § 102 (a)

On page 3, in paragraph 7 of the outstanding Office Action, the rejection of claims 1, 55, 87-90, 92, and 94 under 35 U.S.C. § 102 (a) for allegedly being anticipated over Levine *et al* was maintained. Applicants submit herewith an unexecuted *In re Katz* Declaration by Dr. Carl H. June, one of the co-inventors of the instant application. The Declaration states that the work described in the Levine *et al.* paper is Applicants' own work, published within one year of the filing date of the present application. As such, the reference cannot be properly used as prior art against the Applicants under 35 U.S.C. § 102(a). Applicants will shortly provide an executed copy of this Declaration. Applicants respectfully request withdrawal of this rejection.

Rejection under35 U.S.C. § 102(e)

Claims 1, 55, 60, 75 and 87-89, 92, and 94 were rejected under 35 U.S.C. § 102(e) as purportedly anticipated by Chang (Office Action, page 4, paragraph 8). Applicants respectfully traverse this rejection.

The present invention is drawn to methods for downregulating HIV-1 fusion co-factor expression in a T cell by contacting the T cell with a solid phase surface comprising an anti-CD28 antibody and an anti-CD3 antibody. Applicants respectfully assert that the prior art fails to teach this inventive method.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference. *See Titanium Metals Corp. v.*

Banner, 778 F.2d 775, 781, 227 USPQ (BNA) 773, 778 (Fed. Cir. 1985). In other words, if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art. *See id.* at 781.

Chang does not anticipate the instant invention because the reference fails to teach or suggest the methods as presently claimed. Chang disclosed conjugates including a polymer backbone or microbead and certain binding molecules that are specific for a T cell surface antigen, such as CD3, TCR, CD4, CD8, or CD28 on T cells. Chang stated that the primary use of these immunoregulatory substances if as an immune potentiator which activates and expand T cells. *See* Chang, col. 4, line 66-67. Thus, the claims do not read on the prior art, because there is no teaching or suggestion in the reference that one of ordinary skill in the art would be motivated to pick and choose among the laundry list of potential antibodies for activation of T cells, let alone those which would downregulate HIV-1 fusion cofactor expression in a T cell as required by the claimed methods. Therefore, because the prior art fails to teach or suggest each and every element of the claimed invention, this rejection is in error and Applicants kindly request its removal.

To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d (BNA) 1746, 1749 (Fed. Cir. 1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269, 20 U.S.P.Q.2D (BNA) at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Applicants assert that Chang does not make clear that the missing descriptive matter, *i.e.*, the downregulation of CCR5, is necessarily present in the method described therein, and that it would be so recognized by those of ordinary skill in the art. Without acquiescing in the propriety of the Examiner's rejection, the mere fact that the downregulation of CCR5 may result from the multiple methods contemplated under Chang is not sufficient for establishing inherency.

Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(e).

Rejection under 35 U.S.C. § 103(a)

Claims 1, 55, 60, 75, 91, and 93 were rejected under 35 U.S.C. § 103 (a) as purportedly being obvious over the combination of Levine *et al.* or Chang in view of Shattil (Office Action, page 5, paragraph 10). Applicants respectfully traverse this rejection.

As argued above, Levine *et al.* is not a prior art reference against Applicants' claims. In light of this argument and the concurrently submitted *IN re Katz* Declaration, the rejection of the claims over Levine *et al.* and Shattil is overcome.

As discussed above, Chang does not teach or suggest to one of ordinary skill in the art the claimed method of downregulating HIV-1 fusion cofactor expression in a T cell by contacting the T cell with a solid surface comprising an anti-CD3 antibody and an anti-CD28 antibody. Chang is directed to methods for making immunoregulatory substances from a variety of T cell components, including T cell receptor linked components and T cell surface components or antigens. Applicants submit that Chang was merely an invitation to experiment.

Shattil does not remedy the deficiencies of the primary reference, Chang. Accordingly, Shattil, either alone or in combination with Chang, does not render

the claimed invention obvious. Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

Conclusion

Applicants believe that all of the outstanding rejections of record have been overcome by amendment and/or argument. Accordingly, the claims are now believed to be in condition for allowance. Applicants respectfully request that the Examiner issue a timely Notice of Allowance.

No fees are believed to be due in connection with this correspondence. However, please charge any payments due or credit any overpayments to our Deposit Account No. 08-0219.

The Examiner is invited to telephone the undersigned at the telephone number given below in order to expedite the prosecution of the instant application.

Respectfully submitted,
HALE AND DORR LLP

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Dated: April 9, 2002

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MARKED-UP VERSION OF AMENDED CLAIMS UNDER

37 C.F.R. § 1.121(b)(1)

Please amend claim 91 as described below. As required by 37 C.F.R. § 1.121(b)(1), the amended claim is rewritten below. A marked-up version of the amended claim is attached to show the change relative to the as-filed version.

91. The method of any one of claims ~~1,~~**1 or** 55,~~ 60, or 75,~~ wherein said solid phase surface is a tissue culture dish.